REMARKS

In response to the Office Action mailed 12 August 2005, reexamination and reconsideration of the above-identified application are requested in view of the following amendments and remarks.

Claims

Claims 93, 97-103, 107-130 were previously pending. Claims 97, 107, 122 and 123 have now been canceled, and new claims 131 to 157 have been added.

Accordingly, claims 93, 98-103, 108-121, and 124-157 are pending.

First rejection under 35 USC 112 first paragraph (written description)

Claims 93, 97-103, 107-118, 121, 122 and 124-130 were rejected as failing to comply with the written description requirement, the Examiner stating that the prior amendments to claims 93 and 103 entered new matter.

The Examiner notes that claims 93 and 103 were amended to recite nucleic acids encoding a polypeptide comprising a HER-2/Neu fusion protein, "and not comprising a HER-2/Neu transmembrane domain or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain". The Examiner states that "the part of the fusion proteins ... that is not set forth in the claims structurally is the linker portion", except by the phrase "and not comprising a HER-2/Neu transmembrane domain or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain". The Examiner states that support is not found for the concept of describing the linker in this manner, "because 'any portion' may be equivalent to one amino acid or several amino acids that happen to be found within the intracellular domain and then linked together."

Claims 93 and 103 have been amended to recite the structure of the linker component; the linker is an amino acid sequence of no more than 50 amino acids. Support for these amendments is found in the specification as filed, e.g., at page 8, lines 9-12 and lines 23-25; and page 31, line 11 continuing to page 32.

Claims 93 and 103 have been amended to recite that the claimed nucleic acid molecule encodes a polypeptide comprising (a) a sequence having at least 90% sequence identity to SEQ ID NO:3, where this sequence is capable of producing an immune response against the HER2/Neu extracellular domain in a warm-blooded animal, and (b) a sequence having at least 90% sequence identity to SEQ ID NO:4, and which increases the immunogenicity of (a) in a warm blooded animal. Support for these amendments is found in the specification as filed, e.g., at page 9, line 27 continuing through page 10; page 12, final paragraph continuing through page 13; page 16, final paragraph; page 29, lines 19-31; page 47, line 31 continuing to page 48.

Withdrawal of the present rejection is respectfully requested.

Second rejection under 35 USC 112 first paragraph (written description)

Claims 93, 97-103, 107-118, 121, 122 and 124-130 were rejected as failing to comply with the written description requirement. The Office Action states that the basis for this rejection is that the specification fails to provide support for the claimed genus of nucleic acids encoding fusion proteins comprising at least 90% sequence identity to SEQ ID NO:6 or SEQ ID NO:7.

The Office Action states that, as previously presented, claims reciting "90% identity to" SEQ ID NO:6 or 7 failed to teach the critical features of these sequences that must be included to make a fusion protein which falls within the scope of the claim. The Office Action states that "the claimed fusion proteins encompass a structure that has high similarity to one domain of the fusion protein, fused to, perhaps, only one amino acid from the other domain . . . the specification fails to teach how much of the extracellular or phosphorylation domain may be missing and still be defined as such."

Claims 93 and 103 have been amended to recite structural features for each component of the encoded protein. Component (a) must have at least 90% identity to SEQ ID NO:3 (human HER-2/Neu ECD) and must be capable of producing an immune response to the HER-2/Neu extracellular domain in a warm-blooded animal; component (b) must have at least 90% sequence identity to SEQ ID NO:4 or SEQ ID NO:5 (respectively, the human HER-2/Neu phosphorylation domain and a fragment of human

HER-2/Neu phosphorylation domain), where component (b) increases the immunogenicity of (a) in a warm-blooded animal (increases the immune response). See, e.g., page 12, final paragraph. Components (a) and (b) are linked by an amino acid sequence of no more than 50 amino acids.

Applicants submit that claims 93 and 103 as amended comply with the written description requirement. Both component (a) and (b) are described by structure and by function. The claim does not encompass a structure that has high similarity to one component, while fused to only one or a few amino acids from the other component.

The Office Action further states that "addition of the limitation that the fusion protein be capable of producing an immune response against a HER-2/Neu protein fails to couple the structural characteristics with functional characteristics of the genus." Applicants respectfully dispute this statement as it applies to the presently amended claims. The claims recite a polypeptide comprising three components, each defined by structure (sequence) and function (immune response; linker; enhancement of immune response).

The Office Action further states that the claims appear to contain a contradiction: "the claims are drawn to nucleic acids encoding fusion proteins *consisting of* an extracellular domain and a phosphorylation domain, but ... allow alterations. When is an extracellular domain or a phosphorylation domain an extracellular domain or a phosphorylation domain and when is it not?" Applicants submit that the present claim language obviates this concern.

Withdrawal of the present rejection is respectfully requested.

Objection to claims 119, 120 and 123

Claims 119, 120 and 123 were objected to for depending on rejected claims. Claims 119 and 120 have been amended to independent format. Claim 123 has been canceled.

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Conclusion

Applicants respectfully submit that the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of the application, please do not hesitate to call the undersigned at 919-483-1012.

The Commissioner is hereby authorized to charge any fees required or credit any overpayment to Deposit Account No. 07-1392.

Respectfully submitted,

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I hereby certify that this correspondence is being facsimile transmitted to (571) 273-8300 on 1/23/2006

Patty Wilson